Original Article

Comparison of incidence of sore throat with laryngeal mask airway Protector and laryngeal mask airway ProSeal: A randomised clinical trial

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ABSTRACT

Background and Aims: Postoperative sore throat (POST) can be as high as 42% in supraglottic devices. LMA® Protector™ is a novel second-generation laryngeal mask airway (LMA) with Cuff Pilot™ technology that allows continuous cuff pressure monitoring. Elevated cuff pressure is a risk factor for POST in supraglottic devices, so we conducted this study to determine whether continuous cuff pressure monitoring can alleviate POST. **Methods:** This randomised double-blinded clinical trial compared the incidence of sore throat between LMA® Protector™ and LMA® ProSeal™ and was conducted in 118 patients scheduled for elective short surgical procedures. They were randomised to either LMA® Protector™ (Group PT) or LMA® ProSeal™ (Group P). The airway was secured with either of the two devices. The primary outcome was the incidence of sore throat at 1, 6, and 24 hours postoperatively and compared using the Chi-square test along with other parameters like first attempt success rate and blood staining of the device. The time taken for insertion and oropharyngeal seal pressure were compared using an independent *t*-test. **Results:** The incidence of POST was low with Group PT (12%) compared to Group P (28.8%) ($P = 0.005$). The mean oropharyngeal seal pressure was significantly higher in Group PT than in Group P [33.72 (3.07) versus 27.72 (3.88) cm of H_2O], $P < 0.005$. The first attempt success rate was 81.2% and 100% in LMA® Protector™ versus LMA® ProSeal™. **Conclusion:** LMA® Protector™ had a reduced incidence of POST compared to LMA ProSeal. However, a longer insertion time and difficult placement may be a concern.

Keywords: Laryngeal masks, LMA® ProSeal, LMA® protector, pharyngitis, POST, postoperative, postoperative sore throat, risk factors, supraglottic airway device

INTRODUCTION

Supraglottic airway (SGA) devices are now preferred for short-duration daycare procedures under general anaesthesia. Postoperative sore throat (POST) is a common complication with supraglottic airway devices, and it causes significant patient distress in the perioperative period, thus leading to dissatisfaction with health care, anxiety, and prolonged hospital stay, especially in daycare procedures.[1] The incidence of POST with SGA can be up to 42% lower than the endotracheal tube (ETT).[2-4] Many risk factors are associated with POST. Among these, one potential modifiable factor is the intracuff pressure.[4] Higher cuff pressures, by causing direct compression, can impede the mucosal blood supply, leading to ischemia. The cuff pressure may change at any point, that is, with patient positioning, pneumoperitoneum,

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or using anaesthetic gases like nitrous oxide (N_2O), which can get absorbed and expand the cuff.[5] This validates the need for continuous monitoring of intracuff pressure.[6] Among the newer second-generation SGAs, LMA® Protector™ (Teleflex Medical, Co. Westmeath, Ireland) is a disposable, pre-shaped LMA (laryngeal mask airway) made of silicone with dual gastric channels and gives a higher oropharyngeal sealing pressure (OPSP).[7] It also has an inbuilt Cuff Pilot™ technology, which is colour-coded and facilitates continuous monitoring of intracuff pressures.

We hypothesised that the incidence of POST would be lower with LMA® Protector™ than with LMA® ProSeal™ due to the continuous cuff monitoring facility. Our primary objective was to compare the incidence and severity of POST with the use of LMA® Protector™ and LMA® ProSeal™. The secondary objectives were to compare the device insertion time, first-attempt insertion success rates, ease of insertion, OPSP, and ventilatory parameters in each device.

METHODS

This randomised controlled trial was conducted in a tertiary care centre after obtaining approval from the Institute Ethics Committee (JIP/IEC/2021/029, dated 6 July 2021) and registration with the Clinical Trials Registry-India (CTRI/2022/08/044587, http://ctri.nic.in). From September 2022 to July 2023, 118 patients belonging to the American Society of Anesthesiologists (ASA) physical status I/II and in the age group of 18–60 years were enroled. Patients undergoing elective surgeries lasting up to 2 hours, requiring general anaesthesia with SGA devices, were recruited. Exclusion criteria included patients at risk of aspiration or a recent upper respiratory tract infection history. The study was carried out as per the 1964 principles of the Declaration of Helsinki and its later amendments, 2013, or comparable ethical standards and with adherence to the Consolidated Standards of Reporting Trials (CONSORT) guidelines.[8] Written informed consent was obtained from patients to participate in the study and use patient data for research and educational purposes.

Participants were randomised into either of the two groups using computer-generated random number tables with blocks of variable size by an individual not involved in the study. Allocation concealment was done using sequentially numbered opaque sealed envelopes. Group PT - LMA® Protector™ and Group P - LMA® ProSeal™ were used to secure the airway. The patients were blinded to the device used, but the anaesthesiologist involved in the case could not be blinded.

A day before surgery, eligible patients were explained the study protocol, and written informed consent was obtained. Appropriate fasting guidelines were followed as per institutional protocol. On the day of surgery inside the operating room, standard ASA monitors such as electrocardiogram, non-invasive blood pressure, and pulse oximeter were attached, and the baseline parameters were noted. After pre-oxygenation with 100% oxygen, fentanyl 2 μg/kg and propofol 1–2 mg/kg were administered intravenously till loss of verbal response. Following the ability to mask ventilate, vecuronium 0.1 mg/kg was administered intravenously, and ventilation continued for 3 minutes with 100% oxygen and isoflurane to maintain a minimum alveolar concentration (MAC) of 1. Any use of oropharyngeal or nasopharyngeal airway for mask ventilation was noted. After opening the sealed opaque envelopes, the airway devices were allocated, and the appropriate SGA size was selected per the manufacturer's instructions.

An operator with more than 1 year of experience in SGA insertion was involved in airway management. Operators were trained to use LMA® Protector™ on an airway manikin, followed by supervised patient training. Both SGAs were deflated and lubricated with soluble jelly (KY jelly, Reckitt Benckiser Ltd, India), and the device was inserted in the sniffing position. After pushing the tongue away, LMA® Protector™ was inserted along the curvature of the hard palate, and the device was gently pushed inwards towards the hypopharynx till resistance was felt. The LMA® ProSeal™ was held in a pen-holding position and inserted along the hard palate till resistance was felt. After LMA insertion, the cuff was inflated to maintain a pressure of less than 60 cm of H_2O as measured using a Portex cuff pressure manometer (Smith Medical ASD Inc., Dublin, OH, USA). In the case of the LMA® Protector™, the cuff was inflated till the green-coloured mark in the Cuff Pilot™, and throughout the procedure, the indicator was maintained in the same colour range. According to the manufacturer, the yellow zone corresponds to cuff pressures less than 40 cm of H_2O, the green zone for 40–60 cm of H_2O, the transparent zone for 60–70 cm of H_2O, and the red zone indicates cuff pressures more than 70 cm of H_2O.

A suitable-sized nasogastric tube (14 F) was passed, and its position was confirmed by auscultation on the epigastric region. Ventilation was maintained with a tidal volume of 8 ml/kg and a respiratory rate of 12–14 breaths/minute to target an end-tidal carbon dioxide ($EtCO_2$) in the 35–44 mmHg range. Intraoperatively, anaesthesia was maintained with air and oxygen mixture with isoflurane up to 1 minimum alveolar concentration (MAC). All patients received 1 g intravenous paracetamol intraoperatively. For analgesia, intravenous fentanyl boluses of 20 μg were administered for the rise in heart rate of >20% from the baseline. Once the surgery was over, the residual neuromuscular block was reversed with neostigmine (50 μg/kg) and glycopyrrolate (10 μg/kg). SGA was removed after deflation once the patient became awake and responded to commands. Gentle suctioning was done using a suction catheter only if secretions were present. Any blood staining on the LMA, coughing, or retching was noted. The total duration of the procedure was from the placement of SGA till its removal. If patients reported severe sore throat, intervention in the form of benzydamine gargles and analgesics like intravenous paracetamol was advised.[9] Oral intake of liquids was allowed after 4 hours if not contraindicated from the surgical side. For patients discharged on the day of surgery, a telephonic interview was planned for follow-up.

A blinded investigator assessed the primary outcome of the presence of sore throat after 1 hour in the postoperative recovery room. Severity was graded using a nil/mild/moderate/severe scale. The presence of dysphagia, dysphonia, or any abnormal sensation in the throat was also evaluated. Both the patient and the investigator were unaware of the device used. Similar questions were asked at 6 hours and 24 hours after the surgery. The secondary outcomes, like the time taken for LMA insertion, were measured as the time from the picking up of the device to the appearance of the square wave capnography waveform. The operator graded the ease of device placement using a Likert scale (as easy, moderately difficult, or very difficult). If more than two attempts were taken for insertion, it was considered a failure, and further management was left to the concerned anaesthesiologist. After confirming the correct device placement, the OPSP was measured by closing the adjustable pressure limiting (APL) valve to 40 cm of H_2O, with a flow of 3 litres of oxygen, and the pressure at which airway pressure stabilises or any audible or palpable leak appeared was noted. The ventilatory parameters like $EtCO_2$ and airway pressures were recorded before surgical incision. The number of attempts or any trauma during placement was noted. Any need to reposition the device was noted.

Based on a previous study, the cumulative incidence of sore throat among patients with LMA was 42%.[4] Expecting a reduction in the overall incidence of sore throat in LMA® Protector™ at 24 h to 16% as was observed in a study by Chang *et al*.[10] The minimum expected sample size was calculated to be 108 (54 in each arm) with a power of 80% and an absolute precision of 5% by using OpenEpi software. After considering a dropout rate of 10%, the corrected sample size was calculated to be 118.

The data were entered in a pre-designed Excel Sheet, and statistical analysis was done using Statistical Package for the Social Sciences (Armonk, NY: IBM Corp, USA), Version 19.0. The distribution of categorical variables like gender, sore throat, first-attempt success rate, and blood staining was expressed in frequency and percentage. The comparison of these categorical variables between the groups was carried out by using the Chi-square test/Fisher's test. The distribution of continuous and discrete variables like age, weight, body mass index (BMI), insertion time, oropharyngeal seal pressure, airway pressures, and $EtCO_2$ was expressed in terms of mean with standard deviation or median with interquartile range based on the data distribution. They were compared using an independent Student's *t*-test or Mann–Whitney test. The significance level for all the analyses was set at less than 0.05.

RESULTS

One hundred eighteen patients belonging to ASA I/II were assessed for eligibility, and all were randomised into two groups of 59 patients each [Figure 1]. Patient characteristics like age, weight, and BMI were comparable [Table 1]. Most of our patients were female, as the study was conducted among gynaecologic patients undergoing short laparoscopic procedures or modified radical mastectomy. However, there was no significant difference between the groups. The groups were comparable in terms of the size of the LMA inserted and the duration of surgery [Table 2].

The overall incidence of sore throat with LMA® ProSeal™ was 28.8%, significantly higher than that of LMA® Protector™, 12% ($P = 0.005$). The incidence of

sore throat decreased with time in both groups. At first hour post-operatively, 17 (28%) patients complained of sore throat in the LMA® ProSeal™ group compared to 7 (12%) in the LMA® Protector™ group, which was statistically significant. In the Protector group, two among the seven patients had moderate sore throat, while two had mild symptoms. At 6 and 24 hours post-operatively, the LMA® ProSeal™ group had a higher incidence of sore throat, but it was not statistically significant [Table 3].

The incidence of dysphagia in the first hour was 11.7% and 10.3% in LMA® ProSeal™ and LMA® Protector™ groups, respectively, slightly reducing after 6 hours to 8.47% and 5.17%. We had no patients with dysphonia or hoarseness of voice in either group.

The time taken for insertion was significantly higher in the LMA® Protector™ group, with a mean (SD) of 37.0 (10.7) seconds compared to 23.76 (3.5) seconds in the LMA® ProSeal™ group, $P = 0.005$. The first

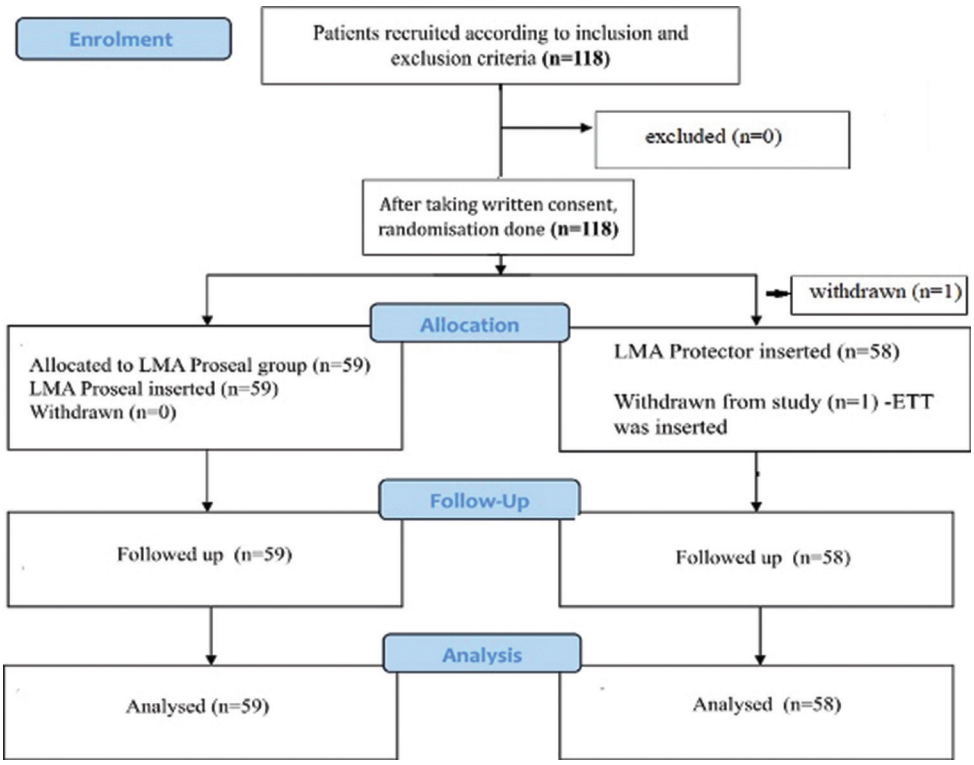

Figure 1: Consolidated standards of reporting trials (CONSORT) flow diagram of the study. LMA = Laryngeal mask airway, ETT = Endotracheal tube

Table 1: Demographic characteristics of the study participants

Variable	Group P (LMA® ProSeal™) *n*=59	Group PT (LMA® Protector™) *n*=58
Age (years); mean (SD)	32.28 (6.2)	31.17 (5.5)
Gender (Female/Male) - *n* (%)	52 (88.1)/7 (11.9)	52 (89.7)/6 (10.3)
ASA physical status I/II- *n* (%)	31 (52.54)/28 (47.46)	31 (53.45)/27 (46.55)
Weight (kg); mean (SD)	60.55 (7.7)	60.84 (7.7)
Body Mass Index (kg/m^2); mean (SD)	24.04 (2.72)	23.96 (3.18)

Data expressed as mean (SD) or number (percentage). ASA=American Society of Anaesthesiologists, SD=Standard deviation, *n*=Number of patients

Table 2: Surgical duration and insertion parameters

Variables	Group P (LMA® ProSeal™) *n*=59	Group PT (LMA® Protector™) *n*=58	*P*	Mean difference (95% CI)/RR (95% CI)
Surgical duration (minutes); mean (SD)	77.2 (31.53)	74.39 (25.71)	0.590	2.81 (-7.74, 13.35)
LMA insertion time (seconds); mean (SD)	23.76 (3.5)	37.01 (10.7)	0.005	-13.25 (-16.21, -10.29)
No of attempt -1/≥2, *n* (%)	59 (100)/0	47 (81%)/ 11 (18.9%)	0.005	
Failed insertions, *n* (%)	0	1	0.490	
Presence of blood staining on LMA, *n* (%)	1 (1.69)	5 (8.62)	0.114	5.05 (0.61-42.21)

Data expressed as mean (SD) or number (percentage). LMA=Laryngeal mask airway, 95% CI/RR=95% confidence interval/relative risk, SD=Standard deviation, *n*=Number of patients

attempt insertion success rate of LMA® Protector™ was 81%, and the second attempt success was 100%. In the case of LMA® ProSeal™, the first attempt success rate was 100%. This difference was found to be statistically significant. Ease of insertion was graded as easy in all patients using LMA® ProSeal™, whereas 81% had easy and 18.9% had moderate difficulty with LMA® Protector™ [Table 4]. Blood staining was noted in 8.6% in group PT and only 1.69% in group P. LMA® Protector™ could not be placed in one patient, and the airway was secured with endotracheal intubation.

The mean (SD) OPSP of LMA® Protector™ [33.72 (3.07) cm of H_2O] was significantly higher than that of LMA® ProSeal™ 27.72 (3.88) cm of H_2O]. However, $EtCO_2$ and peak airway pressures were comparable among both groups [Table 4].

DISCUSSION

We found that the usage of LMA® Protector™ significantly reduced the incidence of postoperative sore throat and pharyngolaryngeal symptoms compared to LMA® ProSeal™ in adult patients undergoing surgical procedures of less than 2 hours. The incidence of dysphagia was also found to be lower but comparable. The ventilatory parameters were comparable, and the OPSP was higher with LMA® Protector™. The ease of insertion was better with LMA® ProSeal™, and so was the first insertion attempt success rate.

LMA® Protector™ is a newer second-generation LMA made of silicon with a novel Cuff Pilot™ technology.[7] This gives the device an added advantage over other second-generation SGA, as high cuff pressures are a risk factor for POST.[11] LMA® ProSeal™, another cuffed second-generation SGA made of similar material, is routinely used in our institute, so we used it for comparison.

Our finding of POST is consistent with Chan *et al*.[6], where a novel LMA with Cuff Pilot™ technology was used for continuous intracuff pressure monitoring, reducing the pharyngolaryngeal symptoms by 34%. This decrease could be explained by the lower cuff pressure in the 40–60 mmHg range in the LMA® Protector™ group, as noted with the Cuff Pilot™ technology. The patients in LMA® ProSeal™ had cuffs inflated up to 60 cm of H_2O, and repeat cuff pressure monitoring was not done. Previous studies have assessed the performance of LMA® Protector™ and found sore throat in the 2.8–33% range up to 24 hours following surgery.[7,12,13] Our finding for the incidence of dysphagia is consistent with previous studies, where dysphagia is reported as 6% and 10.8%.[6,7]

The cuff pressure is a dynamic parameter influenced by factors like nitrous oxide usage, pneumoperitoneum, or Trendelenburg position.[14-16] We did not use nitrous oxide, but most of our patients underwent laparoscopic procedures in the Trendelenburg position, which could have increased cuff pressure intraoperatively.

Table 3: Severity of sore throat over time among LMA® ProSeal™ and LMA® Protector™

Severity of sore throat	Group P (LMA® ProSeal™) *n*=59	Group PT (LMA® Protector™) *n*=58	*P*	RR (95% CI)
1st-hour *n* (%)				
Mild/moderate/severe	17 (28.8)/0/0	5 (8.6)/2 (3.44)/0	0.005	2.33 (1.07, 5.3)
Total	17 (28.8)	7 (12.04)		
6th-hour *n* (%)				
Mild/moderate/severe	12 (20.33)/0/0	4 (6.89)/2 (3.44)/0	0.350	1.96 (0.79, 4.8)
Total	12 (20.33)	6 (10.33)		
24-hour *n* (%)				
Mild/moderate/severe	4 (6.77)/0/0	3 (5.17)/0/0	1	1.31 (0.3, 5.6)
Total	4 (6.77)	3 (5.17)		

RR=Relative risk, 95% CI=95% confidence interval, *n*=Number of patients

Table 4: Comparison of clinical performance and ease of insertion of LMA® ProSeal™ and LMA® Protector™

Variables	Group P (LMA® Proseal™) *n*=59	Group PT (LMA® Protector™) *n*=58	*P*	Mean difference and 95%CI
OPSP (cm of H_2O) mean (SD)	27.72 (3.88)	33.72 (3.07)	0.005	-5.99 (-7.28, -4.71)
$EtCO_2$ (mmHg) mean (SD)	35.06 (1.55)	34.48 (2.46)	0.128	0.58 (-0.17, 1.34)
Ppeak (cm of H_2O) mean (SD)	21.47 (2.64)	21.36 (2.43)	0.811	0.11 (-0.81, 1.04)
Ease of insertion (easy/moderate/difficult), *n* (%)	59 (100)/0/0	47 (81)/11 (18)/0	0.005	

Values are expressed as mean (standard deviation), OPSP=Oropharyngeal sealing pressure; Ppeak=Peak airway pressure; $EtCO_2$=End-tidal carbon dioxide concentration, 95% CI=95% confidence interval, *n*=Number of patients

The constant monitoring of cuff pressures in the LMA® Protector™ group helped to prevent the higher cuff pressures. Regarding ventilatory parameters, LMA® Protector™ gave a significantly better seal than LMA® ProSeal™. These values agree with previous studies where the reported OPSP with LMA® Protector™ is 30-37 cm of H_2O,[7,12,17-19] though some studies have reported a lower OPSP of 25.2 (23-29) cm of H_2O.[13]

The longer insertion time noted in LMA® Protector™ can be due to its larger size and lack of experience with the device. Our insertion times of LMA® Protector™ were similar to that of 31 (26-40) seconds, as noted in the Airway Device Project Evaluation Team (ADEPT) by Difficult Airway Society.[7] In contrast, a few studies have reported shorter insertion times of 14.5-19 seconds.[12,13]

We noted the first attempt success rate of insertion of 100% with LMA® ProSeal™ and 81% with LMA® Protector™, which could be attributed to a lack of experience with the new device. This finding is supported by studies using LMA® Protector™, where they got a first-attempt success rate of 85.6–88.5%.[12,16] On the contrary, Ní Eochagáin *et al*.[7] had a higher success rate of 91.9% at the first attempt.

Chang *et al*.[10] noted that the first-attempt success rate of gastric tube placement in LMA® Protector™ was 49%. The design of the gastric port opening is more slanted and in dorsal position in LMA® Protector™ compared to the LMA® ProSeal™, where it is present at the tip of the cuff. The rims are thicker in ProSeal, but a soft silicone tip is in LMA® Protector™. We found that LMA® Protector™ had a favourable profile regarding post-operative pharyngolaryngeal complaints despite some difficulty in insertion and can be considered a suitable option for an SGA in short-duration procedures.

There are certain limitations to our study. Our study population mainly consisted of female patients without difficult airway predictors. Hence, the results cannot be generalised. The intracuff pressures of the LMA® ProSeal™ group were not monitored in between the procedures, so any change in the cuff pressure over time cannot be assessed. All our patients received neuromuscular blockers, which can impact the overall incidence of sore throat. We did not record the volume of air used to inflate the cuff in either of the groups; only the initial pressure in the ProSeal group and the green line in the cuff pilot were looked for. The experience with using the two devices was different, which could have impacted the first attempt success rate and time for insertion. The inability to blind the performers could affect the insertion parameters.

CONCLUSION

LMA® Protector™, with its continuous cuff monitoring feature, is better than LMA® ProSeal™ regarding postoperative sore throat and other pharyngolaryngeal symptoms. The better OPSP is an added advantage.

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Statement on data sharing

De-identified data may be requested with reasonable justification from the authors (email to the corresponding author) and shall be shared after approval as per the authors' Institution policy.

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Conflicts of interest

There are no conflicts of interest.

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